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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,414	11/09/2006	Todd Campbell	PA1211	4776

28390 7590 12/24/2008
MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

MEDWAY, SCOTT J

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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12/24/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No. 10/527,414	Applicant(s) CAMPBELL, TODD	
	Examiner SCOTT MEDWAY	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03/11/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/11/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 19 recite the limitations "said at least one polymer layer" in lines 1-2 of claim 17 and "said polymer layers" in line 1 of claim 19. There is insufficient antecedent basis for these limitations in the claims since there is no mention of a *polymer* layer in claim 12 on which claims 17 and 19 depend.

Claims 18 and 20-25 inherit the dependency from base claim 17 and are thus rejected accordingly.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 7-13, 15-17 and 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwarz et al (U.S. Pat. 6,368,658 B1, hereinafter “Schwarz”).

Regarding claims 1, 11 and 12 Schwarz discloses methods and apparatuses for the controlled delivery of at least one pharmaceutical compound, comprising an implantable medical device (col. 3, line 52) having a surface and a coating with at least two layers (col. 10, lines 57-60) where one coating incorporates at least a releasable pharmaceutical compound (col. 4, line 37) with another layer having a property affecting the reliability of the compound and where the layer differs from the first layer (e.g. col. 14, lines 23-31). As to claims 11 and 12, Schwarz discloses a number of methods to form coatings (see Examples 1-6) and a method involving implanting the device at a target site (col. 1, lines 26-30).

Regarding claims 2 and 3, the implants may be selected from stents including vascular, biliary and esophageal stents (col. 3, lines 51-55).

Regarding claims 4 and 7, the layer is a polymer such as polyglycolic acid (col. 14, lines 41-55).

Regarding claim 5, since Schwarz discloses a variety of polymers of different molecular weights being displaced on the device and further disclose a number of different degradation profiles based on the type of polymer applied (see Example 4), the Examiner interprets molecular weight to be at least one property which inherently affects the releasability of the pharmaceutical compound.

Regarding claims 8-10, the compound may be rapamycin (col. 4, line 37), which is known to be an anti-restentoc compound and a macrolide antibiotic.

Regarding claims 13 and 15, Schwarz discloses the tubular structure may be a stent (col. 3, lines 51-55), where the stents disclosed by Schwarz are fully capable of being mechanically expanded.

Regarding claim 16, the device may be coated with collagen (col. 6, line 53), which is a known bioresorbable coating.

Regarding claim 17, Examples 1-6 of Schwarz disclose a variety of multi-layered coatings where the coatings are made from different polymers, where the different polymers are known to have different molecular weights (see e.g. col. 14, lines 1-12 where primer coating solution has a different molecular weight from the top-coat solution).

Regarding claim 19, the layer is a polymer such as polyglycolic acid (col. 14, lines 41-55).

Regarding claims 20-25, the compound may be rapamycin (col. 4, line 37), which is known to be an anti-restentoc compound and a macrolide antibiotic, and additionally the pharmaceutical compound may either be contained within the polymer coating or coupled thereto (col. 5, line 61 to col. 6, line 31).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al (U.S. Pat. 6,368,658 B1).**

It is noted that Schwarz does not specifically disclose the molecular weights of the polymer types used for the medical device coating to be in the range of 1 kDa to 100,000 kDa. It would have been obvious to one of ordinary skill in the art at the time of the invention to consider implementing polymer coatings having molecular weights in this range, since it has been held that where the general conditions of a claim are disclosed in the prior art (such as high molecular weight polyglycolic acid coating), discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

9. **Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al (U.S. Pat. 6,368,658 B1) in view of Sirhan et al (U.S. Pat. 6,858,221 B2, hereinafter "Sirhan").**

Regarding claim 14, it is noted that Schwarz does not disclose the stent to be self-expanding. Sirhan discloses a device for delivering a pharmaceutical compound, comprising a stent which may be self-expanding (col. 4, line 29). It would have been obvious to one of ordinary skill in the art at the time of the invention to consider the use of a self-expanding stent, since self-expanding stents are well-known substitutions for other kinds of stents and such an improvement would yield the predictable result of allowing a stent to be expanded in a vessel with minimal effort.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant is directed to the *Notice of References Cited*.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCOTT MEDWAY whose telephone number is (571) 270-3656. The examiner can normally be reached on Monday through Friday, 7:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott J. Medway/
Examiner, AU 3763
12/15/2008

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763